Exhibit 6

U.S. FOOD & DRUG ADMINISTRATION

K212101
Intuitive Surgical, Inc.
Trade/Device Name: da Vinci SP Firefly Imaging System
Contact Name: Connor McCarty

This document is being communicated via e-mail as an attachment. The date on which FDA sent this e-mail is the official date of this correspondence.

We have reviewed your submission K212101 and have determined that additional information is required. Your file is being placed on hold pending a complete response to the attached deficiencies.

Please submit your response, referencing the submission number K212101 to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Please refer to the eCopy guidance at https://www.fda.gov/media/83522/download for current information on eCopy requirements.

Your response is due within 180 days from the date of this request, which is the hold date plus 180 days. If a complete response is not received in CDRH's Document Control Center by this date, we will consider this submission to be withdrawn, and we will delete it from our review system.

You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act.

If you would like a meeting or teleconference with the review team and management to discuss your planned approach for responding to the attached deficiencies, please submit your request for feedback as a Submission Issue Q-Submission (Q-Sub). Please note that a Submission Issue Q-Sub does not take the place of a formal response to this email notification. As noted above, FDA will consider this submission to be withdrawn if FDA does not receive, in a submission to the Document Control Center, a complete response to all of the attached deficiencies within 180 calendar days of the date of this request.

This request for additional information has undergone supervisory review to ensure that the deficiencies cited are least burdensome and relevant to the marketing decision. Please see the revised guidance "Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions" issued on September 29, 2017 (https://www.fda.gov/media/71735/download) for clarification regarding major and minor deficiencies.

MAJOR DEFICIENCY LIST

The Agency has identified a major deficiency that if not adequately resolved, may preclude a favorable decision on the marketing application.

1. In our interactive email dated September 9, 2021, we requested additional clarification regarding the reprocessing instructions in the subject device labeling. Section 6 of your submission stated that other than the subject device endoscope part number, *"there are no other changes to the parent device reprocessing instruction appendices for the subject device."* However, we noticed several differences between the subject device labeling and that of the parent system in K173906:

   a. The recommended number of uses and reprocessing cycles for the system instruments (page 9) are greater than in the same table of the parent system labeling in K173906.

   b. Page 10 lists three cameras: 430060 version -40 and lower, 430060 version -41 and higher, and 430077 version -01 and higher, whereas the parent da Vinci SP system (K173906) reprocessing instructions list only one camera, the 430060 *EndoWrist SP* Camera.

   c. The subject device instructions recommend 12, 20, and 20 uses and 14, 24, and 24 reprocessing cycles for the three cameras, respectively. However, for the camera of the parent system in K173906, 10 uses and 12 reprocessing cycles were cleared after substantive review of the submitted reprocessing data.

   d. Appendix B, pages 15-16 and 21-23 lists Summit Medical Trays IN-8924, IN-8926, IN-8921, IN-8922, IN-8923, IN-8925, IN-8927 which are not included in the parent device (K173906) labeling. The subject device labeling additionally states *"The wrapped foot, container foot, and no foot configurations for the Summit Medical trays listed in this appendix are all validated for use with Intuitive Surgical da Vinci products."*

   Upon further review after our interactive request, we also noted the following:

   e. The recommended dry time in Appendix C is provided as 30-50 minutes, compared to 20 minutes in the previously cleared labeling.

   You replied that these changes were made between K173906 and the current submission without 510(k) clearance on the basis of FDA guidance "Deciding When to Submit a 510(k) for a Change to an Existing Device" and internally documented Non-Filing Justifications 1048606-02 (endoscope version -41), 1048620-01 (reprocessing instructions – sterilization trays), and 1048620-02 (reprocessing instructions – number of uses).

   However, we believe that changes to the reprocessing of your device require a 510(k). Your device falls under the Endoscope and Accessories regulation (21 CFR 876.1500). Per Appendix E of FDA's guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," a System, Surgical, Computer Controlled Instrument (product code NAY) poses a greater likelihood of microbial transmission and represents a high risk of infection if it is not adequately reprocessed. Because of the greater risks to the public health posed by these devices, 510(k) submissions should include protocols and complete test reports of the validation of the reprocessing instructions for us to evaluate substantial

equivalence. Therefore, even if the endoscope validation testing was performed using similar test methodology as described in a previous 510(k) submission, the new reprocessing validation information needs to be included in a 510(k) submission for FDA review.

Please provide the testing and data requested below:

i. You have not provided reprocessing (cleaning and sterilization) validation testing. This information is to support the effectiveness of the increased number of cycles you recommended for the system instruments (Section 6, page 9) and cameras (Section 6, page 10). Note, even if you plan to use an automated Washer-Disinfector, cleaning validation data is needed to validate the efficacy of the automated cleaning process and to demonstrate acceptable cleanliness through the proposed end of device life. This information is requested in accordance with the recommendations in Appendix E of the above guidance.

ii. As stated above, you proposed a modified number of uses and reprocessing cycles for the system instruments (Section 6, page 9) without additional data. Bench validation data or scientific justification is needed to demonstrate that the instruments maintain adequate performance (as defined in your existing instrument validation protocols) after the maximum number of uses and reprocessing cycles.

iii. For the device cameras (Section 6, page 10), you provided some bench validation data supporting their performance after reprocessing. However, it is unclear how many cycles the cameras were reprocessed before testing and if they underwent simulated use testing. Please confirm if the test device was reprocessed to the maximum number of cycles and uses recommended on page 10 in Section 6. If not, please provide bench validation data demonstrating that the camera performance is adequately maintained after the maximum number of uses and reprocessing cycles. Please provide validation for each camera model or justification why a single validated sample is an adequate representation of the worst-case model.

iv. For the Summit Medical Trays listed in Appendix B, pages 15-16 (IN-8924, IN-8926, IN-8921, IN-8922, IN-8923, IN-8925, IN-8927), you have not included validation data as stated above in part (d). Please provide the sterilization validation data you collected to determine that the subject device is adequately sterilized using these trays. Alternatively, please provide the 510k clearance number(s) of the trays, confirmation that the trays were cleared for the specific sterilization method of the subject device, and justification why the clearance is applicable to the unique geometry of the subject device.

v. You have stated a recommended dry time of 30-50 minutes in Appendix C. FDA recommends that "ranges" not be used for defining sterilization cycle parameters (i.e., 30-50 minutes dry time), as this implies that all intermediate values have been validated. It is important that the parameters that have been tested and the results are clearly delineated. Please revise the sterilization dry time instructions to include one discrete time, e.g., the minimum dry time required, in accordance with your validation testing.

If the above validation tests are conducted according to a procedure previously reviewed and found acceptable in a prior submission, please provide the prior submission number and document title/number, a description of the test article and test configuration, a summary of the test results, including numerical

outcomes on objective acceptance criteria, and test conclusions. Otherwise, please provide a complete test report including methods, acceptance criteria, results, and conclusions. Alternatively, please revise the subject device reprocessing labeling to reflect the number of uses and reprocessing instructions that have been previously cleared. This is needed to ensure that the system instruments, cameras, and sterilization trays can be used safely and effectively for the number of uses proposed in Appendix A of your reprocessing instructions.

MINOR DEFICIENCY LIST

The Agency has identified minor deficiencies that can be resolved in a straightforward manner, but that need to be addressed to meet regulatory requirements or to prevent potential misbranding or adulteration.

1. You provided proposed labeling for the subject device in file "554370-01_B_SP Firefly User Manual Addendum.pdf." We compared this document to the labeling of the da Vinci Firefly Imaging System predicate labeling, and found that the following were present in the predicate labeling, but not the subject device labeling:

   a. *"CAUTION: The Endoscope Controller receptacle has a spring-loaded shutter designed to prevent light from exiting the receptacle if no connector is installed. If you observe light coming from the receptacle while no light guide is installed, do not look directly into the receptacle. Avoid direct eye exposure as directed by the yellow warning label on the front of the Endoscope Controller (see Table B.1)."*

   b. *"WARNING: Do not use endoscopes if any part of the system is damaged or does not function properly. Do not attempt to remove the cover from the Endoscope Controller. Refer all servicing to a qualified Intuitive Surgical service representative. Failure to follow this warning may lead to injury to operator or patient."*

   c. On page 21 of the subject device labeling document the "WARNING" symbol is removed from *"Avoid looking at light emitted directly from the endoscope or the light guide, which could cause eye injury. Table B.1 contains specifications for near-infrared (NIR) radiation emitted in Firefly imaging."*

   d. *"CAUTION: Do not examine optical fiber ports or optical fibers that are connected to a light source with optical instruments (for example, a magnifying glass)."*

   Please provide justification why the above cautions and warnings are not applicable to the subject device or are otherwise addressed in other sections of the labeling. Alternatively, please add the above to the subject device labeling. This is needed to determine that the subject device labeling has adequate warnings and cautions and is substantially equivalent to the predicate device labeling.

2. The Non-clinical and/or Clinical Tests Summary & Conclusions section of your proposed 510(k) Summary states *"Bench testing and clinical validation testing on the subject device confirmed that no issues of safety or effectiveness."* However, we typically do not consider human factors evaluation or animal testing to be "clinical validation." Referring to clinical validation may mislead readers to believe that a clinical trial or other human clinical data was provided to support substantial equivalence in your

submission. Therefore, please revise this sentence to refer to "bench testing, usability testing, and animal validation testing" rather than clinical validation. This is needed so the 510(k) Summary does not imply that a clinical study was provided in the submission.

FDA is offering a teleconference within 10 calendar days from the date on this letter to address any clarification questions you may have pertaining to the deficiencies. If you are interested in a teleconference, please provide (1) proposed dates and (2) a list of your clarification questions via email at least 48 hours before the teleconference to the lead reviewer assigned to your submission. We would like to emphasize that the purpose of the meeting is to address specific clarification questions. Please note that if the specific clarification questions are not received at least 48 hours before the teleconference, the review team might not be able to provide feedback. The teleconference is not intended for review of new information, test methods or data; these types of questions could be better addressed via a Submission Issue Q-Submission (Q-Sub). For additional information regarding Q-Subs, please refer to the Guidance for Industry and FDA Staff on Medical Devices: Requests for Feedback and Meetings for Medical Device Submissions at https://www.fda.gov/media/114034/download.

Least Burdensome (LB) Flag

The LB flag is an approach to allow submitters the opportunity for the informal review by or on behalf of Division management of an issue raised in an FDA request for additional information (i.e., a deficiency letter). The goal of the LB flag is to quickly address FDA requests that submitters do not believe are least burdensome or when submitters believe they are being held to a different standard than their legally marketed predicate device. The LB flag is not intended to clarify deficiencies, is not an appeal under 21 CFR 10.75, and is not intended to provide a review of a proposed response to deficiencies.

If you would like to throw the LB flag, FDA has several criteria that should be met before you submit your request:

- You should have tried to address your concern by discussing it with Division management before attempting to throw the LB flag. This discussion with Division management may take place as part of a teleconference (such as the voluntary teleconference held within 10 days following transmission of an Additional Information letter to clarify deficiencies), email, or a Q-Submission Submission Issue Request.
- Your flag should generally be limited to two topic areas. Topic areas are common premarket review deficiency categories that apply to many device types across multiple reviewing Divisions. Examples of topic areas include biocompatibility, sterility, reprocessing, software, electromagnetic compatibility, wireless, electrical safety, clinical, and non-clinical performance testing.
- If you would like to discuss issues pertaining to more than two topic areas, you should contact OPEQSubmissionSupport@fda.hhs.gov for more information.
- You should throw the LB flag within 60 calendar days of the date that FDA sent the deficiency letter.

Upon meeting the criteria, you should send a short email (e.g., 1-2 page) that includes: 1) a summary of the deficiencies under disagreement, 2) a summary of relevant communications with Division management, and 3) a proposed path forward. The LB flag should be sent to the lead reviewer and their Assistant Director. You should also copy OPEQSubmissionSupport@fda.hhs.gov on your LB flag email request. Within two business days of your email, your request will be acknowledged by the reviewing Division. If you do not meet the criteria for the LB flag, you will be notified in this acknowledgement email.

Your LB flag should contain sufficient information to determine whether the deficiency letter was not least burdensome, or you are being held to a different standard than your predicate device. FDA may request a phone call with you to discuss your concern further and intends to communicate feedback from Division management on LB flags through email no later than 21 calendar days of their receipt. Please note that the LB flag does not change the deadline for your response to the Document Control Center. If you have any questions, please contact OPEQSubmissionSupport@fda.hhs.gov.